

## **REMARKS/ARGUMENTS**

### **I. Status of the Claims**

Upon entry of the present amendment, claims 1, 2, 4-6, 14-16, 22 and 23 are pending. Claims 3, 7-13 and 17-21 have been canceled without disclaimer or prejudice to renewal. Claims 1, 2, 4-6, 14-16 are amended. New claims 22 and 23 have been added.

Claim 1 is amended to recite “an anti-CD61 antibody” in place of “a substance,” which finds support in original claim 3 (now canceled) and throughout the specification. The anti-CD61 antibody heavy and light chain variable region amino acid sequences have been specified by reciting “wherein not more than 10% of the number of amino acids are mutated by deletion, addition, insertion, and/or substitution;” support for which can be found in the specification on page 12, lines 35-36.

Claim 2 is amended to “an anti-CD61 antibody” and incorporates the limitations of original claims 11 and 13 (now canceled).

Claims 4 and 5 are amended to properly depend from claim 1 or 2.

Claim 6 is amended to “a composition” comprising the antibody of claim 1 or 2. Support is found in original claim 14.

Claims 14 and 15 are amended to recite “a chimeric or humanized” anti-CD61 antibody “or a derivative thereof.” Support is found in the specification on page 8, lines 34-35 and page 10, line 30 to page 12, line 31.

Claim 16 is amended to recite “wherein the method comprises a step of administering to a subject in need thereof, an anti-CD61 antibody or a derivative thereof.” Support is found on page 20, lines 20-23 of the specification.

Claims 22 and 23 are newly added with subject matter corresponding to “a pharmaceutical composition” of claims 14 and 15.

No new matter is added by the present amendments.

## **II. Application Papers**

In the Office Action Summary the Examiner did not indicate acceptance of the drawings. The applicant kindly requests the Examiner acknowledge acceptance of the drawings by checking Box 10(a) in the subsequent Office Action.

## **III. Priority Under 35 U.S.C. § 119**

In the Office Action Summary the Examiner did not acknowledge the foreign priority claim of the present application. The applicant kindly requests the Examiner acknowledge the priority claim by checking Box 12(a) in the subsequent Office Action.

## **IV. Claim Rejections**

### **A. Written Description and Enablement Rejections**

Claims 1-6 and 10-16 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description and enablement requirements. The Examiner alleges that *“the claims are drawn to a genus of substances that is defined only by functionality. The only structure disclosed is the antibody #33 for which the sequences of the variable heavy and light chains as well as the sequences of all CDRs are presented.”* And further

*“the claims are drawn to antibodies that are either described by one CDR only (claims 11 or 13) or by heavy or light chains comprising a number of undisclosed deletions, substitutions or additions to the respective SEQ IDs without any indications which are residues that are necessary for the functionality of the antibody and which are invariable. Thus, the claims are drawn to a genus of antibodies that is defined only by functionality only without any indication of a structural determinant of this functionality (without the exception of the Antibody #33).”*

The Examiner also alleges that *“the specification, while being enabled for an anti-CD61 antibody, does not reasonably provide enablement for any other substance, or a*

*derivative thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims."*

Claims 1 and 2 are amended and now limited to an anti-CD61 antibody which has been defined by the sequences of the variable regions of both the heavy and light chains or the sequences of all the CDRs. Furthermore, claim 1(b) and (d) is limited to an antibody with no more than 10% of the amino acids of the variable region of the heavy and/or light chain mutated by deletion, addition, insertion and/or substitution. Consistent with these changes, claims 4-6 and 14-16 are amended and claims 10-13 canceled.

#### **B. Indefiniteness Rejection**

Claims 1-6 and 10-16 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner further alleges that independent claims 1 and 10-13 are indefinite because they lack adequate written description so as to allow the metes and bounds of the claims to be determined. Claim 6 is rejected as being indefinite because "an inhibitor" is not a composition. Furthermore, claim 16 is rejected as being incomplete for omitting essential steps.

The rejected claims are now amended. These amendments render the rejections moot. The claimed subject matter is sufficiently described in the specification and is enabling for a person skilled in the art to carry out the present invention.

#### **C. Novelty Rejection**

Claims 1-6 and 14-16 are rejected under 35 U.S.C. § 102(e) as anticipated by Mills *et al.* (Mills)(US Pub. 20070190078). Additionally, Claims 1-6 and 10-16 are rejected under 35 U.S.C. § 102(b) as anticipated by Reiner *et al.* (J. Immunol. Meth. 184:153-162 (1995)) and Dingivan (US Pub. 20030044406).

### **1. 102(e) Rejection**

First, in response to 102(e) rejection based on Mills, the applicant submits a verified English translation of the Japanese priority document (JP2004-010971; attached Appendix A)) filed on January 19, 2004. The claimed invention finds support in the priority document.

The PCT application corresponding to the Mills US application was filed October 14, 2004 and claims priority under 35 U.S.C. § 119 to Irish Application No. 2003/0761 filed October 14, 2003. Under applicable rules, a foreign priority date under 35 U.S.C. § 119 cannot be used to antedate an application filing date for prior art purposes. MPEP 2136.03, *see In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966). Therefore, the Mills' application filing date of October 14, 2004 is after the priority date of the present application and cannot anticipate the present invention under 102(e). The applicant respectfully requests this rejection be withdrawn.

### **2. 102(b) Rejection**

As described above, claims 1, 2, and 4-6 have been amended and are now drawn to a specific anti-CD61 antibody by reciting the amino acid sequences from Antibody #33. Claims 14 and 15 are amended to recite a chimeric or humanized anti-CD61 antibody as an active ingredient.

Reiner *et al.* does not teach the anti-CD61 antibody #33, of the present invention, a chimeric or humanized anti-CD61 antibody, nor an anti-CD61 antibody having an activity to suppress any cytokine release, anti-inflammatory activity or anti-hypercytokinemia activity.

Dingivan discloses antibodies which bind to integrin  $\alpha_v\beta_3$  (LM609 and VITAXIN<sup>TM</sup>) but not an antibody specific to the CD61 antigen which is a monomer. As described in Wilder (page ii96, left column, second paragraph, lines 25-27; filed with the IDS submitted on October 19, 2007; a copy of which is provided as a courtesy to the Examiner in Appendix B), the anti- $\alpha_v\beta_3$  antibodies Dingivan discloses, LM609 and MEDI-522, bind specifically to a conformation formed by the heterodimerization of CD51 ( $\alpha_v$ ) and CD61 ( $\beta_3$ )

antigens, but not to the CD61 antigen as a monomer. Thus, Dingivan never teaches an antibody which specifically binds to CD61 antigen, and is irrelevant to the present invention.

The rejection is rendered moot in view of the amendments made.

**D. Obviousness Rejection**

Claims 1-6 and 10-16 are also rejected as being obvious in light of Dingivan.

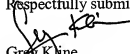
As discussed above, Dingivan does not teach and anti-CD61 antibody. A skilled artisan reading Dingivan could not have arrived at the present invention.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

  
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